§ 522.1962

- (2) Steers—(i) Amount. 200 milligrams of progesterone and 20 milligrams of estradiol benzoate per dose.
- (ii) *Indications for use.* For increased rate of weight gain and improved feed efficiency.
- (iii) *Limitations.* (A) For animals weighing 400 pounds or more; for subcutaneous ear implantation, one dose per animal.
- (B) For additional improvement in rate of weight gain in steers fed in confinement for slaughter, reimplant at approximately day 70.

[40 FR 13858, Mar. 27, 1975, as amended at 48 FR 48659, Oct. 20, 1983; 49 FR 13873, Apr. 9, 1984; 51 FR 21746, June 16, 1986; 52 FR 45312, Nov. 27, 1987; 53 FR 7406, Feb. 21, 1989; 55 FR 13769, Apr. 12, 1990; 59 FR 49808, Sept. 30, 1994; 61 FR 5507, Feb. 13, 1996; 62 FR 8372, Feb. 25, 1997]

§ 522.1962 Promazine hydrochloride injection.

- (a) *Specifications.* Each milliliter of sterile aqueous solution contains 50 milligrams of promazine hydrochloride.
- (b) Sponsor. In §510.600(c) of this chapter, see No. 000008 for conditions of use as in paragraph (c)(1)(i) of this section; see No. 000856 for conditions of use as in paragraph (c)(1)(ii) of this section; see No. 000864 for conditions of use as in paragraph (c)(1)(iii) of this section.
- (c) Conditions of use. (1)(i) To horses either intramuscularly or intravenously at a dosage of 0.2 to 0.5 milligram per pound of body weight, and to dogs and cats 1 to 3 milligrams per pound of body weight, every 4 to 6 hours as a tranquilizer or preanesthetic.¹
- (ii) To horses either intramuscularly or intravenously at a dosage of 0.2 to 0.5 milligram per pound of body weight, and to dogs and cats at 1 to 2 milligrams per pound of body weight, every 4 to 6 hours as a tranquilizer, preanesthetic, for minor operative procedures in conjunction with local anesthesia, as adjunctive therapy for tetanus, and as an antiemetic in dogs and

(iii) To horses intravenously at a dosage of 0.2 to 0.5 milligram per pound of body weight, as a tranquilizer and

cats prior to worming, or to prevent

body weight, as a tranquilizer and preanesthetic, as required.¹

motion sickness in dogs.1

- (2) Not for use in conjunction with organophosphates because their toxicity may be potentiated, nor with procaine hydrochloride as its activity may be increased.¹
- (3) Not for use in horses intended for food. 1
- (4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.¹

[46 FR 18962, Mar. 27, 1981]

§ 522.2002 Propiopromazine hydrochloride injection.

- (a) Chemical name. 1-Propanone, 1-[10-[3-(dimethylamino) propyl] phenothiazine-2-yl]-, monohydrochloride.
- (b) Specifications. Propiopromazine hydrochloride injection contains 5 or 10 milligrams of the drug in each milliliter of sterile aqueous solution.
- liter of sterile aqueous solution. (c) Sponsor. See No. 000856 in §510.600(c) of this chapter.
- (d) Conditions of use. (1) It is administered either intravenously or intramuscularly to dogs and cats for tranquilization at a dosage level of 0.05-0.5 milligram per pound of body weight and is also administered intravenously to dogs and cats as a preanesthetic at a dosage level of 0.25 milligram per pound of body weight.
- (2) It is not to be used in conjunction with organophosphates and/or procaine hydrochloride since phenothiazines may potentiate the toxicity of organophosphates and the activity of procaine hydrochloride.
- (3) For use only by or on the order of a licensed veterinarian.

[40 FR 13858, Mar. 27, 1975, as amended at 46 FR 60570, Dec. 11, 1981; 61 FR 5507, Feb. 13, 1996]

§522.2005 Proposol injection.

- (a) *Specifications.* The drug is a sterile, nonpyrogenic, oil-in-water emulsion containing 10 milligrams of propofol per milliliter.
- (b) Sponsor. See No. 000061 in §510.600(c) of this chapter.

¹These conditions are NAS/NRC reviewed and found effective. Applications for these uses need not include effectiveness data as specified by §514.111 of this chapter, but may require bioequivalency and safety information.

- (c) Conditions of use—(1) Dogs. (i) The drug is indicated for use as an anesthetic as follows: As a single injection to provide general anesthesia for procedures lasting up to 5 minutes; for induction and maintenance of general anesthesia using incremental doses to effect; for induction of general anesthesia where maintenance is provided by inhalant anesthetics.
- (ii) The drug is administered by intravenous injection as follows: For induction of general anesthesia without the use of preanesthetics the dosage is 5.5 to 7.0 milligrams per kilogram (2.5 to 3.2 milligrams per pound); for the maintenance of general anesthesia without the use of preanesthetics the dosage is 1.1 to 3.3 milligrams per kilogram (0.5 to 1.5 milligrams per pound). The use of preanesthetic medication reduces propofol dose requirements.
- (iii) Adequate data concerning safe use of propofol in pregnant and breeding dogs have not been obtained. Doses may need adjustment for geriatric or debilitated patients. Federal law restricts this drug to use by or on the order of a licensed veterinarian.
 - (2) [Reserved]

[61 FR 66582, Dec. 18, 1996, as amended at 62 FR 61625, Nov. 19, 1997]

§ 522.2012 Prostalene solution.

- (a) *Specifications.* Each milliliter of sterile solution contains 1 milligram of prostalene.
- (b) *Sponsor.* No. 000856 in §510.600(c) of this chapter.
- (c) Conditions of use—Horses. (1) It is used in mares for the control of estrus.
- (2) It is administered at a dose of 5 micrograms per kilogram of body weight as a single subcutaneous injection.
- (3) Not for use in horses intended for food.
- (4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.
- [41 FR 26854, June 30, 1976, as amended at 61 FR 5507, Feb. 13, 1996]

§ 522.2063 Pyrilamine maleate injection.

(a) *Specifications.* The drug is a sterile aqueous solution with each milliliter containing 20 milligrams of pyrilamine maleate.

- (b) Sponsors. See No. 000061 in \$510.600(c) of this chapter for uses in paragraph (c)(2)(i) of this section; see No. 000864 in \$510.600(c) of this chapter for uses in paragraph (c)(2)(ii) of this section.
- (c) Conditions of use. (1) It is intended for treating horses in conditions in which antihistaminic therapy may be expected to lead to alleviation of some signs of disease.
- (2)(i) It is administered intramuscularly, subcutaneously, or intravenously. Local injection at the site of insect bites may be indicated in severe cases. Intravenous injections must be given slowly to avoid symptoms of overdosage. Dosage may be repeated every 6 to 12 hours whenever necessary. Horses, 40 to 60 milligrams per 100 pounds body weight; foals, 20 milligrams per 100 pounds body weight.
- (ii) It is administered intravenously. Intravenous injections must be given slowly to avoid symptoms of overdosage. Dosage may be repeated every 6 to 12 hours if necessary. Horses, 40 to 60 milligrams per 100 pounds body weight; foals, 20 milligrams per 100 pounds body weight.
- (3) Do not use in horses intended for food purposes.
- (4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13858, Mar. 27, 1975; 41 FR 9150, Mar. 3, 1976, as amended at 42 FR 13549, Mar. 11, 1977; 42 FR 61256, Dec. 2, 1977; 51 FR 41477, Nov. 17, 1986; 52 FR 7832, Mar. 13, 1987; 54 FR 1164, Jan. 12, 1989]

§ 522.2095 Sarafloxacin solution for injection.

- (a) Specifications. Each milliliter contains sarafloxacin hydrochloride equivalent to 50 milligrams of sarafloxacin in a 20 percent propylene glycol solution.
- (b) *Sponsor*. See No. 000074 in §510.600(c) of this chapter.
- (c) *Related tolerances*. See §556.594 of this chapter.
- (d) *Conditions of use.* 18-day embryonated broiler eggs and day-old broiler chickens:
- (1) Amount—(i) 18-day embryonated broiler eggs: 0.05 milligram sarafloxacin in 0.1 milliliter dose in single in ovo injection.